

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO ETHICON WAVE 4 MOTIONS	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE
CERTAIN GENERAL OPINIONS OF JERRY BLAIVAS, M.D.**

Defendants Ethicon, Inc., Ethicon LLC, and Johnson & Johnson (hereinafter “Defendants”) submit this memorandum in support of their motion to exclude certain general opinions of Jerry G. Blaivas, M.D., with respect to the cases set forth in Exhibit A to Defendants’ accompanying motion.

INTRODUCTION

Dr. Blaivas is a New York urologist who has experience treating patients with stress urinary incontinence (“SUI”) and pelvic organ prolapse (“POP”) and who has experience removing sling systems. Ex. A to Ex. B, TVT Report, CV.¹ Dr. Blaivas intends to provide general opinions about TVT, TVT-O, TVT Secur, TVT Exact and TVT Abbrevio (collectively “the TVT Devices”), used to treat SUI, as well as Prolift, which is used to treat POP. Ex. B-G, Expert Reports. As set forth below, the Court should preclude Dr. Blaivas from testifying about matters that are beyond his expertise, that are unreliable, that are irrelevant, and/or that are otherwise improper.

¹ Exhibits cited in this brief are the exhibits filed in support of Defendants’ Wave 1 motion to exclude Dr. Blaivas (*see* Doc. 2038), except for Exhibit A, which is attached hereto. Because most of Dr. Blaivas’s opinions about the TVT Devices are the same, citations in this brief are generally limited to his TVT report (Ex. B).

LEGAL ARGUMENT

Defendants incorporate by reference the standard of review for *Daubert* motions set forth by the Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D.W. Va. 2014).

I. The Court should preclude Dr. Blaivas from testifying that TVT Devices are not safe in the treatment of SUI.

Dr. Blaivas admits that TVT has been a “gold standard” in the medical profession for the surgical treatment of SUI, that it has been studied more than any other device or procedure for this intended use, and that more physicians use synthetic slings to treat SUI than other methods. Ex. H, Sept. 2015 Dep. 72:8-13, 78:17-24, 100:23-101:8, 173:16-23. Indeed, Dr. Blaivas helped formulate SUI guidelines for the American Urological Association (“AUA”), which concluded that TVT and other polypropylene midurethral slings are a suitable surgical option for the treatment of SUI, and he recently co-wrote an article finding that the mesh in TVT Devices is the “optimal” type of mesh to be used. *Id.* at 98:7-99:20, 153:16-21; Ex. 4 thereto, p. 11; Ex. 5 thereto. Yet, he now claims that TVT Devices’ complication rates are high and that they are unsafe. As set forth below, Dr. Blaivas’s opinions are unreliable and should be excluded.

A. Dr. Blaivas’s opinions about TVT Devices are premised on an unreliable assessment of complications and complication rates.

The Court should preclude Dr. Blaivas from testifying that TVT Devices are unsafe, because his opinions about TVT Device complications and complication rates are unreliable. In *In re: Ethicon Inc Pelvic Repair Sys. Prods. Liab. Litig.*, 2016 WL 4500767, at *4 (S.D. W.Va. Aug. 26, 2016), the Court excluded these opinions, primarily because: “Dr. Blaivas continues to rely quite heavily on complication rates this court has excluded time and again,” and because he “does not provide a reasonable explanation for his disagreement with guidelines that he helped author and that conclude mesh products are suitable surgical options.” Dr. Blaivas’s opinions

and the bases for his opinions in this wave of cases are identical, and the Court should similarly preclude Dr. Blaivas's opinions in these cases.

1. "Unreliable Minimum 12.5% Complication Rate Opinions"

Dr. Blaivas apparently intends to testify that TVT Devices have a minimum 12.5% complication rate based on a 2015 review article that he co-wrote with Dr. Vladimir Iakovlev and others titled "Safety considerations for synthetic sling surgery." Ex. H, Sept. 2015 Dep. 118:19-120:4; Ex. 4 thereto, pp. 6, 21. Therein, Dr. Blaivas and his colleagues concluded that "a minimum of 12.5% of women who undergo [synthetic midurethral sling surgery] have a serious adverse event and/or surgical failure." *Id.* The Court should find that this opinion is unreliable.

When asked recently about his opinion concerning complication rates in the *Huskey* case, Dr. Blaivas conceded that it was impossible for him to accurately opine about synthetic mesh complication rates. *See Huskey*, 29 F. Supp. 3d at 721 (excluding opinion based on Dr. Blaivas's uncertainty). Given this admission, Dr. Blaivas may not, a few months later, purport to be certain about TVT complication rates. The Court should apply its ruling in *Huskey* to this case.

Dr. Blaivas's 2015 review article does not change the result in *Huskey*, because there is no indication that the 12.5% complication rate estimated in that article has any semblance of reliability. That article (headed by a team of Plaintiffs' experts in this mesh litigation) is equivocal and lacks reliability on its face. For instance, the review article does not even set forth the methodology by which the 12.5% figure was derived.

Moreover, Dr. Blaivas's review article cherry picks the data, failing to take into account long-term studies finding TVT complication rates to be much lower. At Table 1 of the article, the authors collected 11 studies purportedly meeting the criteria for inclusion. Ex. 4 to Sept. 2015 Dep., (Ex. H) pp. 3, 21; Ex. H, Sept. 2015 Dep. 84:4-15, 107:18-19. When asked whether it would "concern [him] if there were more than ten other TVT retropubic studies with five-years

duration or more that [he] did not include in that table in [his] review article,” Dr. Blaivas conceded that he would “want to see them.” *Id.* at 120:7-11. During his deposition, Dr. Blaivas was confronted with long-term studies that were not identified in Table 1, that met the criteria of the report, and that Dr. Blaivas admitted were “very good” and/or “well done.” *Id.* at 109:7-113:22, 179:1-4; 180:9-12, 185:13-189:4, 192:12-195:7, 198:24-206:22, 213:9-10, 367:9-386:6; Ex. 12-14, 25-27 thereto. In fact, the report omitted 20 studies which, perhaps not surprisingly, reflect a complication rate well lower than 12.5%. Dr. Blaivas could not explain why these studies were not cited in the table, he agreed that it was “painful” for him not to know, during a break in the deposition he called a co-author to try to figure out why they were excluded, and finally acknowledged that he and his co-authors committed an “error” by excluding them. Ex. H, Sept. 2015 Dep. 115:23-117:18, 193:23-194:2, 199:7-17, 201:16-17, 205:7-12, 325:17-340:3, 372:18-373:2, 382:4-6.

In fact, Dr. Blaivas’s own review paper states that the Type I mesh in TVT Devices is “optimal” as compared to other mesh and has lower complication rates than Type II to IV meshes. Ex. 4 to Sept. 2015 Dep. (Ex. H), p. 11; Ex. H, Sept. 2015 Dep. 123:5-15, 124:8-11, 126:1-127:3, 143:4-144:9, 141:2-12. Yet, Dr. Blaivas lumps TVT Devices with all of these other mesh devices in projecting (apparently out of thin air) a 12.5% complication rate. Under these circumstances, Dr. Blaivas’s study and other studies that at best simply measure the complication rates of *all* synthetic mesh are flawed and unreliable, and Ethicon should not be prejudiced by poorer outcomes of non-midurethral devices or its competitors’ products.

2. *Flawed Assessment of Pain, Dyspareunia & Sexual Dysfunction Data*

Dr. Blaivas’s perception of TVT Device complications is also inconsistent with medical literature that he, himself, helped formulate. For instance, Dr. Blaivas’s opinions about the rate of pain, dyspareunia, and sexual dysfunction associated with SUI surgical procedures is

inconsistent with his own 2015 review article and the AUA guidelines. The AUA guidelines that Dr. Blaivas helped create based on numerous studies reported that only 1% of all midurethral synthetic sling patients experience pain and 0% experience sexual dysfunction. Ex. H, Sept. 2015 Dep. 153:16-21, 158:12-159:8; Ex. L, Apx. A16. By comparison, the AUA reported that 10% of autologous sling patients report pain and that 8% report sexual dysfunction (with Burch complications slightly lower). *Id.*; Ex. H, Sept. 2015 Dep. 164:2-165:16.

Claiming “I don’t know how this occurred,” Dr. Blaivas testified that “I’m confident that nobody on that committee would say that there is a zero incidence of sexual dysfunction and a 1 percent incidence of pain after midurethral sling.” Ex. H, Sept. 2015 Dep. 161:24-162:14. Aside from the impropriety of Dr. Blaivas testifying about what others supposedly “would say,” Dr. Blaivas cannot reconcile such an assertion with the fact that *none* of the panelists referenced any disagreement with these figures in the AUA guidelines. The AUA guidelines explicitly offered the contributors the opportunity to connote that “[a]lthough this estimate is based on some published data, the panel believes the estimates are not consistent with their experience,” and *no such connotation was placed* with respect to this data (although the connotation was made with respect to other data in the guidelines). *Id.* at 159:11-160:4, 163:6-164:1; Ex. L, Apx. A16.

3. *Flawed Assessment of Erosion/Exposure/Extrusion Data*

Dr. Blaivas acknowledged that the medical literature (including his own article) has shown that the rate of exposure for the mesh in TVT Devices is “low” and less than 2.5%. Ex. H, Sept. 2015 Dep. 172:13-173:11, 224:19-16, 296:12-297:1, 346:18-22; Ex. 4 thereto, p. 5. During his deposition, Dr. Blaivas was presented with an article from the esteemed Society of Gynecologic Surgeons (“SGS”) detailing the results of a systematic review of randomized controlled trials for SUI procedures. Ex. H, Sept. 2015 Dep. 281:13-286:23; Ex. 20 thereto. Based on numerous studies assessing thousands of patients, the group found that the risk of

exposure for retropubic synthetic slings (such as TVT) was 1.4%, as compared to 5.4% for autologous slings. *Id.* at 296:12-297:6; Ex. 20 thereto, p. 1.e7. Dr. Blaivas was “incredulous” about this data during his deposition, but he could not offer an explanation other than that it was inconsistent with what he has personally encountered. Ex. H, Sept. 2015 Dep. 297:20-299:15, 428:23-429:12, 432:11-15. Dr. Blaivas may not credibly distinguish these studies merely by stating that they do not comport with his personal experiences. Again, Dr. Blaivas’s “fail[ure] to account for contrary scientific literature” renders his opinions unreliable. *Winebarger*, 2015 WL 1887222, at *10; *Cisson v. C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 606 (S.D. W. Va. 2013).

4. *Selective Choosing*

Dr. Blaivas’s aforementioned omission of several long-term studies in his review article illustrates his pattern of discounting contrary medical literature without adequate explanation. As another example, Dr. Blaivas was asked about a comprehensive meta-analysis performed by Novara and others comparing autologous slings with synthetic slings. Ex. 29 to Sept. 2015 Dep. (Ex. H). Faced with that paper’s report that randomized control trials demonstrated that autologous slings had a higher reoperation rate than synthetic slings, Dr. Blaivas responded that “I do not have any confidence that they – that they did the analysis correctly.” *Id.* at 224-26; Ex. H, Sept. 2015 Dep. 276:5-21. Yet, when asked to explain the basis for his skepticism, Dr. Blaivas made conclusory, illogical and unsupported assertions that the paper had “contradictions,” which he was unable to identify. *Id.* at 276:13-279:5; *see also id.* at 302:1-24.

In support of its findings about alleged TVT Device complications, Dr. Blaivas’s 2015 review article cites a paper by Abbott and others. Ex. B, TVT Report at n. 20, n. 55; Ex. H, Sept. 2015 Dep. Ex. 21. The Abbott paper (which distinguished SUI sling mesh devices from prolapse device mesh devices) reported that “those women with complications after a sling-only procedure were treated more often with medical treatment first and *rarely* required surgical

reintervention.” *Id.* at 163.e6 (emphasis added). Although Dr. Blaivas agreed that this finding is “consistent with the literature,” he nevertheless, “take[s] issue with it.” Ex. H, Sept. 2015 Dep. 314:16-315:9. For grounds, Dr. Blaivas claimed to have read other literature that found differently, but he could not identify any such alleged. *Id.* at 315:16-316:12.

As this Court noted in *Winebarger*, 2015 WL 1887222, at *8, “[a]n expert’s opinion may be unreliable if he fails to account for contrary scientific literature and instead “selectively [chooses] his support from the scientific landscape.” (Citations omitted). Dr. Blaivas has achieved the conclusion that he wants to achieve by cherry-picking favorable portions of certain papers while arbitrarily rejecting unfavorable portions of those same papers. In the same manner, he has arbitrarily discounted other studies that do not comport with the opinions he would like to offer in this case. His opinions are unreliable and should be excluded.

B. Dr. Blaivas has employed a different standard in the courtroom.

The Court should, alternatively, prohibit Dr. Blaivas from testifying that TVT Devices are unsafe, because he has used a different standard than he has used in his professional practice. In a 2013 article published by *The Journal of Urology*, Dr. Blaivas and his co-authors state that “[t]he etiology of mesh sling complications is a matter of conjecture” and that surgeons may be to blame. Ex. I, *et al.*, “Salvage Surgery after Failed Treatment of Synthetic Mesh Sling Complications,” *The Journal of Urology*, v. 190, p. 1284 (2013). To the extent that he departs from that opinion now, Dr. Blaivas is applying standards in this litigation different than the standards that he applies in his medical practice. *See* Ex. J, Dec. 15, 2014 Dep. 391:14-392:12. This is strictly forbidden by *Daubert*. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999) (stating that an expert must “employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field”).

For these same reasons and based on this same article, this Court recently precluded Dr. Blaivas from testifying that polypropylene mid-urethral slings are unsafe for surgically treating SUI. *Wilkerson*, 2015 WL 2087048, at *15. The Court noted that Dr. Blaivas admitted that he employs a different standard for medical literature than he employs when providing opinions in litigation. *Id.* (citing Ex. J). Based on Dr. Blaivas's admissions, the Court should preclude him from providing such testimony in these cases.

II. The Court should preclude Dr. Blaivas from testifying that traditional surgical approaches are a safer alternative to the devices at issue.

Although Dr. Blaivas admits that TVT is as efficacious as alternative procedures for the surgical treatment of SUI, he claims that autologous slings are safer. Ex. H, Sept. 2015 Dep. 81:17-83:1, 103:21-22; Ex. B, TVT Report at II.23-27.² Dr. Blaivas also suggests that other repair procedures, such as anterior colporrhaphy, which sutures the vagina to bone in order to lift the urethra, are a safer alternative to Prolift. Ex. G, Prolift Report at 4, 13-15. As set forth below, these opinions should be excluded because they are irrelevant and unreliable.

A. Safer alternative procedures do not qualify as safer alternative designs.

Though this Court has sometimes reserved ruling on the relevance of experts' "alternative procedures" opinions to design defect claims, preferring case-by-case assessment,³ this Court's recent decisions in two other cases involving an Ethicon vaginal mesh implant demonstrates why such opinions are not relevant here.

In *Mullins v. Johnson & Johnson*, this Court concluded under West Virginia law that "an alternative, feasible design must be examined in the context of products—not surgeries or

² Dr. Blaivas does not perform Burch colposuspension; he has acknowledged that it is not as effective as TVT and autologous slings; he has acknowledged that he is generally unfamiliar with data/literature concerning the Burch procedure; and he has not indicated that he would consider it to be a feasible alternative to TVT. Ex. H, Sept. 2015 Dep. 17:12-21, 20:7-10, 82:20-23, 150:12-15, 152:11-18, 165:11-16, 189:5-190:6, 211:16-23, 215:2-8.

³ See, e.g., *Ethicon Inc. Pelvic Repair Syst. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4500765, at *3 (S.D.W. Va. Aug. 26, 2016).

procedures.” *Mullins v. Johnson & Johnson*, 2017 WL 711766, at *2 (S.D.W. Va. Feb. 23, 2017). Following the Fourth Circuit’s decision in *Talley v. Danek Med., Inc.*, 179 F.3d 154 (4th Cir. 1999), which rejected evidence of surgical alternatives to a spinal fixation device, this Court explained:

Evidence that a surgical procedure should have been used in place of a device is not an alternative, feasible design in relation to the TVT. Whether an alternative procedure could have been performed without the use of the TVT does nothing to inform the jury on the issue of an alternative, feasible *design* for the TVT. Instead, alternative surgeries or procedures raise issues wholly within the context of what a treating physician has recommended for patients based on the individual needs and risk factors associated with individual patients. In other words, alternative surgeries or procedures concern the medical judgment of the doctors who use TVT devices to treat stress urinary incontinence (“SUI”); other surgeries or procedures do not inform the jury on *how* the TVT’s design could have feasibly been made safer to eliminate the risks that caused the plaintiffs’ injuries.

This Court recently reached the same conclusion in *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2017 WL 1264620 (S.D.W. Va. Mar. 29, 2017). Excluding the general expert testimony of Dr. Nathan Goodyear on this issue in Wave 2 cases, this Court noted, “alternative procedures/surgeries do not inform the issue of whether an alternative design for a product exists.” *Id.* at *3. Such testimony is plainly irrelevant and inadmissible.

As was the case in *Mullins* and with Dr. Goodyear’s testimony, alternative surgical procedures distract from the requisite analysis because they say nothing about the availability of a technically feasible alternative product design or formulation. Dr. Blaivas’s safer-alternative procedures opinion should therefore be excluded in its entirety because an alternative method of treatment is not an alternative design that can support a design defect claim.

B. Dr. Blaivas’s opinions are grounded on his unreliable perception of TVT Device complication rates.

Dr. Blaivas’s opinion that autologous slings are safer than TVT Devices is unreliable, because it is premised on an unreliable assessment of TVT Device complication rates for the

reasons set forth in Section I.A above. Because those opinions are unreliable, Dr. Blaivas's opinions about the comparative benefits of traditional surgical approaches are also unreliable.

C. Dr. Blaivas improperly bases his opinions about the benefits of autologous slings solely on his own unreliable personal experiences.

Dr. Blaivas's opinions about autologous slings are inadmissible because they are unreliable. With rare exceptions, Dr. Blaivas only uses autologous fascia pubovaginal slings for the surgical treatment of SUI, and he has never implanted a TVT device. Ex. H, Sept. 2015 Dep. 14:19-24, 17:12-21, 25:9-17, 36:5-6. In support of his statement that "serious complications do not occur or occur very rarely" with autologous slings, Dr. Blaivas cites one article that reports his own personal experiences. Ex. B, TVT Report at II.26; Ex. M.⁴ According to Dr. Blaivas, he has had great success with the manner by which he implants autologous slings, his patients have encountered few complications, and, "in the hands of good surgeons," autologous slings are as effective as TVT. Ex. H, Sept. 2015 Dep. 213:22-214:3, 215:9-17, 264:15-20; Ex. B, TVT Report at II.23-27. When confronted with medical literature showing that the complication rates for autologous slings are comparable to and/or higher than synthetic sling patients, however, Dr. Blaivas could only respond that the data "does not comport with any experience I've had." Ex. H, Sept. 2015 Dep. 291:24-300:5.

It is utterly unreliable for Dr. Blaivas to base his comparison of synthetic slings with autologous slings on his own personal experiences with autologous slings.⁵ Dr. Blaivas has not compared experiences of patients implanted with a TVT by Dr. Blaivas (there are none) with patients implanted with an autologous sling by Dr. Blaivas. Instead, he is making an "apples and oranges" comparison of the experiences of *other physicians'* synthetic sling patients solely with

⁴ Footnote No. 47 in Dr. Blaivas's report also references an article by Roberta Blandon, but that article deals with pelvic organ prolapse and does not address autologous sling complication rates. (Ex. N).

⁵ Although Dr. Blaivas suggests that his opinions are also premised on the notion that, had colleagues encountered complications, he would have heard about it (*see* Ex. H, Sept. 2015 Dep. 405:7-17), this is a far cry from reliable scientific methodology.

his own autologous sling patients, even though Dr. Blaivas's skills and experience may not be representative. In fact, Dr. Blaivas has even written in a published piece that

pubovaginal fascial sling for stress urinary incontinence has never achieved widespread popularity. We believe that the operation lacks popularity because the complication rate, particularly in the hands of inexperienced surgeons, is probably much higher than reported in the literature.

Ex. O; *see also* Ex. H, Sept. 2015 Dep. 79:1-5, 105:14-19, 218:18-219:15, 221:16-222:23, 264:15-20, 300:10-15, 434:16-435:3 (acknowledging that he does not know what percentage of surgeons use autologous slings, that other surgeons implant autologous slings in many different ways, that "few people do the surgery" the way that he performs it, that autologous sling patients of other surgeons likely have higher complication rates than his patients, and that he is unsure how common certain aspects of the procedure are done). According to Dr. Blaivas, autologous sling surgery is "an operation where kind of everybody does it whatever way they want," as compared to synthetic sling surgery, which is "pretty consistent in its efficacy, surgical technique and the complication rates." *Id.* at 265:23-266:15.

Therefore, it is wholly speculative and improper for Dr. Blaivas to leap to the conclusion that the patients of other autologous sling surgeons in this country have experienced complication rates similar to his patients. In fact, Dr. Blaivas has acknowledged that the literature shows that other autologous sling patients generally have less favorable outcomes than Dr. Blaivas's patients. *See, e.g.,* Ex. H, Sept. 2015 Dep. 297:2-301:12, 306:19-23. Dr. Blaivas cannot be certain of his own patients' complication rates, because, in Dr. Blaivas's own words, "many, if not most, patients who experience complications do not return to their original implanting surgeons, contributing to a misperception among individual physicians that their outcomes are better than they, in fact, are." Ex. B, TVT Report at II.30.

Dr. Blaivas has also admitted that there are no reliable medical studies demonstrating that his personal success with autologous slings is consistent with the experiences of other surgeons. Dr. Blaivas testified that “I would want to see about a decade”-long study to make meaningful conclusions about SUI surgery options. Ex. H, Sept. 2015 Dep. 86:17-21. Dr. Blaivas, however, stated that he was unaware of *any* decade-long autologous sling studies. *Id.* at 86:22-88:2. Nor is he aware of any randomized controlled trials that have assessed autologous slings based on a duration of more than five years, and he has not published any of his own experiences with autologous slings involving a duration of more than five years. *Id.* at 91:3-10, 217:14-19.

Asked to “characterize the overall quality of evidence for autologous pubovaginal slings,” Dr. Blaivas stated that “[i]n general, I would say poor.” *Id.* at 97:20-98:5; *see also id.* at 290:13-291:4 (noting that there were only five autologous sling randomized controlled trials available to be addressed in a SGS systematic review, that “it’s the best you can do, but they are hardly convincing to me,” and that “it’s unconvincing data to me”). Thus, just as Dr. Blaivas does not believe that there are reliable studies that refute his opinions about autologous slings, he has indicated that he does not believe that they are reliable studies that support his opinions.

Moreover, Dr. Blaivas is not sufficiently familiar with the available medical literature comparing autologous slings with TVT Devices and other synthetic slings. Although Dr. Blaivas acknowledged that the medical literature shows that autologous slings have a higher reoperation rate than synthetic slings, he stated that “I haven’t looked at it in enough detail to see whether or not I think the methodology would support it.” Ex. H, Sept. 2015 Dep. 280:24-281:11. *See also id.* at 105:11-14, 106:1-17 (stating that he believed that unidentified “current studies” would show that autologous slings did not lead to heightened complications, but cautioning that “I would need to see those papers to answer your question”).

In support of his opinion that serious complications are much easier to treat than complications for synthetic mesh patients, Dr. Blaivas cites two papers: (a) his own 2011 report; and (b) an article by Blandon and others. Ex. B, TVT Report at II.26 & n. 47; Ex. M & N. The Blandon article does not even involve SUI surgeries, and instead, “describe[s] complications associated with the use of transvaginal mesh for treatment of *pelvic organ prolapse*.” Ex. N, p. 523 (emphasis added). Dr. Blaivas’s 2011 article only reports his personal experiences, and it states that “[t]his article provides an update on the surgical technique and long-term outcome of the full-length autologous rectus fascial sling in the treatment of women with *sphincteric incontinence*,” not SUI. Ex. M, p. 7 (emphasis added).⁶ In fact, Dr. Blaivas has acknowledged that the medical literature indicates that “those women with complications after a sling-only procedure were treated more often with medical treatment first and rarely required surgical reintervention.” Ex. H, Sept. 2015 Dep. 314:16-315:9; Ex. 21 thereto, p. 163.e6.

In *Winebarger*, this Court found that an expert “may not solely rely on his personal observations, especially when he seeks to provide broad opinions.” 2015 WL 1887222, at *10. *See also Cisson*, 948 F. Supp. 2d at 606 (finding that an expert’s calculation of complications rates based on his personal experiences “has no basis in any reliable methodology”). Here, Dr. Blaivas seeks to offer broad opinions about autologous slings that are based on his personal experiences that are not corroborated by scientific studies. Accordingly, this does not satisfy the rigors of *Daubert* scrutiny and should be excluded. Alternatively, the Court should reserve ruling on this issue consistent with its decision in *In re: Ethicon*, 2016 WL 4500767, at *3.

⁶ Sphincteric incontinence, also known as intrinsic sphincter deficiency (“ISD”), is somewhat different than SUI. Whereas SUI entails leakage from such functions as laughing, coughing, as exercising, ISD is attributable to low leak pressure and leakage is not brought on by any particular activity. TVT Devices are designed to treat SUI, and autologous slings historically have been procedures used to treat ISD or severe SUI. Ex. O & P.

III. The Court should preclude Dr. Blaivas from testifying that other synthetic mesh devices offer safer alternatives.

In his reports, Dr. Blaivas asserts that “[t]he design of the Gynecare TVT [and other TVT Devices] is flawed.” *See, e.g.*, Ex. B, TVT Report at II.35; Ex. C, TVT-O Report at II.51. When Dr. Blaivas was questioned about his design opinions during his deposition, Plaintiffs’ counsel objected “to this whole line of questioning as beyond the scope,” and Dr. Blaivas stated that “I hadn’t ever thought about [sharing design opinions] in public.” Ex. H, Sept. 2015 Dep. 129:4-12. Thus, Plaintiffs may concede that Dr. Blaivas will not offer such opinions. In any event, Dr. Blaivas is not qualified to offer these opinions, he has not indicated with reasonable medical certainty that other mesh products are safer, and his opinions are unreliable.

A. Dr. Blaivas is not qualified.

There is nothing about Dr. Blaivas’s background, training or experience that affords him expertise to provide design opinions. Dr. Blaivas has no expertise in biomaterials or polymer chemistry. Further, he has not conducted studies to compare the weight and pore size of TVT mesh to the mesh in other commercially available devices. He has never treated a patient for SUI or POP with a lighter weight larger pore mesh and cannot identify anyone else who ever has.

Further, Dr. Blaivas has never performed an analysis in which he “ascertain[ed] the number and body of literature on, specifically, the TVT,” and he has not reviewed any literature or conducted any other evaluation to compare TVT with other mesh products. Ex. H, Sept. 2015 Dep. 100:7-14, 142:7-16, 144:14-16. As Dr. Blaivas candidly admitted: “Unfortunately, I just didn’t look at the literature comparing TVTs to other [mesh] products.” *Id.* at 142:13-16. Therefore, there is no reliable basis for him to compare TVT with other mesh devices at trial.

This Court has repeatedly found that “Dr. Blaivas lacks the ‘knowledge, skill, experience, training or education’ as to product design that *Federal Rule of Evidence 702* requires” and that

his experience removing mesh devices and observing complications does not render him qualified to provide opinions concerning design. *Tyree*, 54 F. Supp. 3d at 561; *Wilkerson*, 2015 WL 2087048, at *15. Dr. Blaivas has not had any experiences since those rulings that would suddenly make him competent to opine about product design.

B. Dr. Blaivas’s weight/pore size opinions are unreliable.

In his reports, Dr. Blaivas suggests that devices with lighter weight, larger pore-sized mesh are preferable alternatives. Ex. B, TVT Report at II.54-55, 57; Ex. G, Prolift Report at 3-4. Yet, Dr. Blaivas’s suggestions about alternative mesh are inconsistent with his own 2015 review article. Ex. H, Sept. 2015 Dep., Ex. 4. In that article, Dr. Blaivas stated that Type I mesh, which is knitted monofilament, macro-porous mesh is considered to be the “*optimal*” mid-urethral sling “owing to its large pore size.” *Id.* at 11; Ex. H, Sept. 2015 Dep. 123:5-15 (emphasis added). Dr. Blaivas has acknowledged that the Prolene mesh in TVT Devices is a knitted monofilament, macro-porous Type I mesh, that Type I mesh is the “preferred” material, and that it is “well documented” that Type I mesh has higher cure rates and lower complication rates than other meshes. Ex. H, Sept. 2015 Dep. 124:8-11, 126:1-127:3, 143:4-144:9, 141:2-12.

Dr. Blaivas conceded that he is uncertain whether meshes that are lighter and more macroporous are preferable, stating that there is not “enough data” to draw “meaningful conclusions.” Ex. H, Sept. 2015 Dep. 124:16-125:14, 141:18-142:5. He could not identify any synthetic sling on the market that has a lower rate of scar contraction and a lower rate of inflammation than TVT, and he stated that “[t]he methodology is not adequate to make those conclusions, in my judgment.” *Id.* at 144:10-145:7.

Recently, this Court precluded Dr. Blaivas from offering these exact opinions, finding they were unreliable because he “never explains how this uncertainty expressed in [his] 2015 article . . . has been dispelled” and he could not “explain the import of the medical literature he

cites to support his expert testimony.” *In re: Ethicon*, 2016 WL 4500767, at *3. For these same reasons, the Court should prohibit Dr. Blaivas from offering these same opinions in these cases.

Further, Dr. Blaivas has suggested that the mesh in the devices at issue would have less inflammation if made of larger pore, lighter weight mesh, but he points to no studies, testing, or other scientific evidence whatsoever that these devices would have been equally effective as a treatment for SUI or POP if the mesh had those characteristics. In fact, when asked how he would change the design of TVT to reduce the risk of inflammation, erosion, and contraction, Dr. Blaivas responded: “That’s for them to figure out.” Ex. H, Sept. 2015 Dep. 140:19-141:1.

C. Dr. Blaivas’s opinions about the cutting of TVT Device mesh are unreliable.

Dr. Blaivas suggests that either laser-cut mesh or mechanically-cut mesh is preferable, apparently depending on which type of mesh was not implanted in Plaintiff. Ex. B, TVT Report at II.47-53. Any suggestion that either laser-cut mesh or mechanically-cut mesh provides a safer alternative lacks a reliable, scientific foundation. Nor has he compared mechanically-cut mesh with laser-cut mesh, and he cites no scientific studies or experiences to support his opinions.

Further, Dr. Blaivas has been playing both sides of the fence. He cannot simultaneously argue that mechanically-cut mesh is less safe than laser cut-mesh and that laser-cut mesh is less safe than mechanically-cut mesh. If the Court permits Dr. Blaivas to offer opinion testimony critiquing mechanically-cut mesh, it should preclude him from referencing laser-cut mesh as a viable alternative design, and vice versa. *See Huskey*, 29 F. Supp. 3d at 712-13 (precluding expert from testifying that laser-cut mesh was preferable given vague, noncommittal testimony). The Court should exclude Dr. Blaivas’s opinions on the cutting of the mesh at this time, or, alternatively reserve ruling on this issue as in *In re: Ethicon*, 2016 WL 4500767, at *3.

D. Dr. Blaivas's opinions about TVT implantation design are unreliable.

Dr. Blaivas believes Ethicon should have designed TVT for a “top to bottom” implantation approach, rather than a “bottom to top” approach, due to a risk of organ perforation. Ex. B, TVT Report at II.17-18; Ex. H, Sept. 2015 Dep. 131:21-132:18. Yet, Dr. Blaivas's criticism is completely refuted by the fact that Ethicon, unbeknownst to Dr. Blaivas, marketed a “top to bottom” TVT device. Ex. Q, Elliott Sept. 26, 2015 Dep. 51:13-17, 78:22-23; Ex. H, Sept. 2015 Dep. 136:4-8. Regardless, Dr. Blaivas could not cite any data to support his opinion that a “top to bottom” approach leads to fewer complications, and he was unaware of any randomized control trials that supports his opinion. *Id.* at 136:9-18.

In fact, a Cochrane study upon which Dr. Blaivas has relied actually concluded that the “top to bottom” approach advocated by Dr. Blaivas was less effective and had more complications than the TVT “bottom to top” approach. *Id.* at 136:22-140:18; Ex. 5 thereto. Dr. Blaivas has relied on another study which concluded that retropubic trocar passage does not have a statistically significant increased odds ratio risk. Ex. H, Sept. 2015 Dep. 243:13-244:20; Ex. 18 thereto, p. 1169. Dr. Blaivas, thus, has selectively chosen information from studies and has not offered any reliable explanation for his failure to credit contrary evidence. *Winebarger*, 2015 WL 1887222, at *8.

E. Dr. Blaivas's opinions about the size of surgical trocars are unreliable.

Dr. Blaivas has also criticized the design of the surgical trocars as “too big, too thick and too pointed” and claimed that the “blind passage” technique of TVT implantation is such that it also heightens the risk of bladder and urethra perforation. Ex. B, TVT Report at II.16-17, Ex. H, Sept. 2015 Dep. 127:23-128:14, 132:19-133:10. Dr. Blaivas, however, stated that “I don't think I can say in words very succinctly what needs to be done,” as it relates to the trocar design. *Id.* at 128:23-129:1. In his report, Dr. Blaivas cites only two articles in support of the notion that

“[t]here is ample evidence in the literature that it is very common for the trocars to inadvertently puncture the bladder or urethra during trocar passage.” Ex. B, TVT Report at II.16, citing Ex. R&S hereto. One of these articles is based on laparoscopic surgery, which has *nothing* to do with synthetic mesh device implantation. Ex. R; Ex. H, Sept. 2015 Dep. 148:13-149:12. The other article relates to the transobturator approach rather than the TVT approach (which uses retropubic passage), and in any event, did not show a statistically significant distinction. Ex. S.

F. Dr. Blaivas’s opinions about TVT-O and TVT-Abbrevio are unreliable.

In Section II.5 of his TVT-O report, Dr. Blaivas claims that TVT-O increases the risk of certain injuries and in Section II.36 of his TVT-Abbrevio report, Dr. Blaivas states that “the shorter length of the laser cut mesh in the TVT Abbrevio leads to more complications.” Ex. C&F. Dr. Blaivas cites no studies in support of these conclusory statements. His later assertion is based solely on one internal Ethicon document, which lends no support to the assertion. Ex. T, ETH.MESH.09911296. Given the utter lack of methodology in support of these opinions, the Court should reject them as unreliable.

IV. The Court should exclude Dr. Blaivas’s product warning opinions.

Dr. Blaivas makes a number of criticisms of Ethicon’s alleged lack of warnings, including in its IFUs. Ex. B, TVT Report at II.33-38; Ex. G, Prolift Report at 3, 11-12. Dr. Blaivas has conceded that he is not an expert in developing warnings for medical devices and that he is unfamiliar with regulations governing warnings for medical devices. Ex. V, Aug. 13, 2015 Dep. 316:12-317:1. Consistent with its ruling in *In re: Ethicon*, 2016 WL 4500767, at *4, the Court should find that “Dr. Blaivas does not possess the additional expertise to offer expert testimony about what an IFU should or should not include.”

V. The Court should limit Dr. Blaivas's biomaterials opinions, such as testimony about alleged mesh degradation, shrinkage, and other deformations.

Dr. Blaivas claims that the mesh in the devices at issue is incompatible with the human body, but he fails to cite a single study in support. Ex. B, TVT Report at II.66; Ex. G, Prolift Report at 3, 7. He also asserts that degradation of the mesh occurs as a consequence of particle loss and other alleged defects in the mesh and that the mesh shrinks, curls, ropes, stiffens and undergoes other deformations *in vivo*. Ex. B, TVT Report at II.55-57, 60. The Court should exclude these opinions because Dr. Blaivas is unqualified and his opinions are unreliable.

A. Dr. Blaivas is not qualified.

Because he is not a bio/polymer chemist and has no background in polymer science, Dr. Blaivas is not competent to testify about issues involving molecular weight, tensile strength and oxidative degradation. Dr. Blaivas has not performed any testing on polypropylene meshes and has deferred to others. Ex. U, Jan. 2014 Dep. 458:12-459:8, 465:8-466:2, 482:2-484:20. In fact, he acknowledged that “the biochemistry and stuff was over my head” and that “I think experts that are more expert at this than me should look into this in more depth.” *Id.* at 482:12-13, 484:17-19. *See also* Ex. V, Aug. 13, 2015 Dep. 196:17-19, 212:17-23, 274:24 - 276:19 (conceding lack of expertise in this area and deferring degradation questions to a pathologist or biomaterials expert).

On at least two different occasions, this Court has precluded Dr. Blaivas from testifying about mesh degradation and shrinkage because his report did not disclose any experience with these alleged issues. *See Tyree*, 54 F. Supp. 3d at 562; *Huskey*, 29 F. Supp. 3d at 722. Once again, Dr. Blaivas's expert reports in these cases do not set forth any personal experience to demonstrate that he is competent to testify about these biomaterials issues, and he has conceded that he is not qualified. Accordingly, the Court should exclude these opinions.

B. Dr. Blaivas's opinions are unreliable.

Even if Plaintiffs could show that Dr. Blaivas is qualified to testify on these matters, his opinions are unreliable. In support of his blanket statements, Dr. Blaivas merely regurgitates studies that are misleading. Dr. Blaivas's reliance on these studies is misplaced, and his conclusory opinions about degradation are unreliable. For instance, the studies cited in Dr. Blaivas's TVT report are geared toward generic polypropylene, rather than the TVT mesh at issue that contains Prolene mesh. Ex. B, TVT Report at II.59-61. As such, Dr. Blaivas's conclusory opinions are inadmissible speculation. *See In re Digitek*, 821 F. Supp. 2d at 839.

Further, the basis for Dr. Blaivas's contention that polypropylene is incompatible with the human body is an MSDS for "polypropylene resin" – not polypropylene and certainly not Prolene, which is a specially formulated form of polypropylene with antioxidants added. Ex. B, TVT Report at II.66; Ex. W, ETH.MESH.02026591. Dr. Blaivas has performed no methodological analysis of this claim. In the absence of any showing of the reliability of these opinions, they should be excluded. *See In re: Ethicon*, 2016 WL 4500767, at *4.

VI. The Court should preclude testimony about inflammatory alleged conditions.

Consistent with its prior rulings, the Court should preclude Dr. Blaivas from testifying about cancer and other alleged complications that a particular Plaintiff has not suffered or in which a competent physician has not testified that a Plaintiff likely will face in the future. *See, e.g., In re: Ethicon*, 2016 WL 4500767, at *5. Even Dr. Elliott concedes that alleged carcinogenic effects, which can lead to sarcomas, may not even be a risk to humans, and even if it is, the risk is likely to be "very low." Ex. G, Prolift Report at 14. The Court should similarly preclude Dr. Blaivas from using the inflammatory and prejudicial terms, "meshology" and "mesh cripples." *See id.*; Ex. B, TVT Report at II.13.

VII. The Court should not allow Dr. Blaivas to testify about testing.

Dr. Blaivas's reports make a number of criticisms about a perceived lack of testing. *See, e.g.,* Ex. G, Prolift Report at 6; Ex. B, TVT Report at II.2, II.40. He also speculates that "[a]ppropriate and unbiased clinical testing, if performed, would have shown the problems and complications associated with synthetic slings, like the Gynecare TVT." *Id.* at II.40. As this Court has repeatedly determined, "[t]here is no indication in the record that Dr. Blaivas has any experience or knowledge on the appropriate testing a medical device manufacturer should undertake." *In re: Ethicon*, 2016 WL 4500767, at *5; *Huskey*, 29 F. Supp. 3d at 723.

VIII. The Court should preclude Dr. Blaivas from suggesting "industry manipulation."

Dr. Blaivas makes sweeping statements about "industry manipulation of data" and that "Ethicon colluded with" other medical device manufacturers "to influence reimbursement for mesh procedures." Ex. G, Prolift Report at 4, 19-20; Ex. B, TVT Report at II.41, 43. Dr. Blaivas does not identify any support whatsoever for his collusion and "industry manipulation" accusations, and therefore, these opinions should be excluded as unreliable and prejudicial.

IX. The Court should disallow other improper opinions.

Consistent with its prior rulings, the Court should preclude Dr. Blaivas from: (a) testifying about Ethicon's alleged knowledge and conduct, *In re: Ethicon*, 2016 WL 4500767, at *6; (b) parroting facts found in corporate documents, *id.*, and (c) criticizing Ethicon's marketing tactics, *See, e.g.,* Ex. G, Prolift Report at 4, 15, *Huskey*, 29 F. Supp. 3d at 723.

CONCLUSION

For the foregoing reasons, the Court should limit Dr. Blaivas's general opinions consistent with the above.

Respectfully Submitted,

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**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO ETHICON WAVE 4 CASES	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on this date, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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